

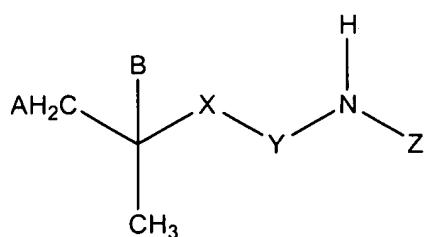
IN THE CLAIMS:

Claims 35, 37-42, 44-55, and 57 are proposed to be amended herein. Please note that all claims currently pending and under consideration in the above-referenced application are shown below. Please enter these claims as amended. This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

Claims 1-34 (Canceled)

35. (Currently amended) An oral sustained-release pharmaceutical composition comprising a core matrix comprising (1)-a therapeutically effective amount of an active compound and (2)-a gelling agent, wherein the amount of said the active compound represents from about 40-70%-40% to about 70% by weight of the oral-sustained release pharmaceutical composition, and wherein said the active compound is selected from the group consisting of: isovaleric acid, a pharmaceutically acceptable salt of isovaleric acid, a pharmaceutically acceptable ester of isovaleric acid, a compound having the structure:



wherein A = H, CH₃, or OH,

B = H, OH, or CH₃,

X = CH₂, CHCH₃, C(CH₃)₂, -O-, CH(OH), or -CH₂O-,

Y = -CO-, or -SO₂-, and

Z = H, CH₂CO₂H, or CH₂CONH₂,

and a compound selected from the group consisting of isovaleramide, 2-methylisovaleramide, 3-methylisovaleramide, 2,2-dimethylisovaleramide, 2,3-dimethylisovaleramide, 4-methylisovaleramide, 2,4-dimethylisovaleramide, 3,4-dimethylisovaleramide, 2,2,4-

trimethylisovaleramide, 3-hydroxyisovaleramide, 4-hydroxyisovaleramide, 4-hydroxy-3-methyl-isovaleramide, 2-hydroxyisovaleramide, N-(2-acetamido)isovaleramide, 2-methyl-1-propylsulfonamide, 1-methylethyl sulfamate, 2-methyl-1-propyl sulfamate, isopropyl carbamate, and isobutylcarbamate.

Claim 36 (Canceled)

37. (Currently amended) ~~A-The oral sustained-release pharmaceutical composition according to claim 35, wherein said the oral sustained-release pharmaceutical composition releases said the active compound at a rate sufficient to maintain a therapeutically effective serum concentration of said the active compound for at least 8 hours.~~

38. (Currently amended) ~~A-The oral sustained-release pharmaceutical composition according to claim 35, wherein said the oral sustained-release pharmaceutical composition releases said the active compound at a rate sufficient to maintain a therapeutically effective serum concentration of said the active compound for at least 12 hours.~~

39. (Currently amended) ~~A-The oral sustained-release pharmaceutical composition according to claim 35, wherein said the gelling agent comprises xanthan gum.~~

40. (Currently amended) ~~A-The oral sustained-release pharmaceutical composition according to claim 35, wherein said the oral sustained-release pharmaceutical composition has a film-coating that retards access of liquids to the active compound and/or retards release of the active compound through the film-coating.~~

41. (Currently amended) ~~A-The oral sustained-release pharmaceutical composition according to claim 35, further comprising one or more excipients at least one excipient.~~

42. (Currently amended) ~~A-The oral sustained-release pharmaceutical composition according to claim 35, wherein said the active compound is isovaleramide.~~

Claim 43 (Canceled)

44. (Currently amended) A The oral sustained-release pharmaceutical composition according to claim 40, wherein said film coating the film-coating comprises a polymeric coating material.

45. (Currently amended) A The oral sustained-release pharmaceutical composition according to claim 44, wherein said the polymeric coating material comprises a mixture of ethyl cellulose and hydroxypropyl methylcellulose.

46. (Currently amended) A The oral sustained-release pharmaceutical composition according to claim 44, wherein said the polymeric coating material further comprises a plasticizer.

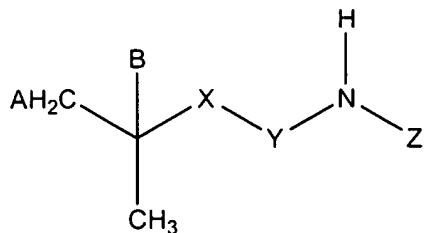
47. (Currently amended) A The oral sustained-release pharmaceutical composition according to claim 35, wherein the oral sustained-release pharmaceutical composition is in the form of a tablet, capsule, or multiparticulate composition.

48. (Currently amended) A process for preparing an oral sustained-release pharmaceutical composition comprising a core matrix comprising (1) a therapeutically effective amount of an active compound and (2) compound, a gelling agent, and (3) optionally one or more substances at least one substance that further retards the release of the active compound, the method comprising:

(a) mixing together a therapeutically effective amount of an active compound with a gelling agent and optionally one or more substances at least one substance that further retards the release of the active compound, and

(b) compressing or extruding said the active compound, gelling agent, and at least one optional substances substance that acts to sustain release of the active compound, wherein the amount of said the active compound represents from about 40-70% 40% to

about 70% by weight of the oral sustained-release pharmaceutical composition, and wherein the active compound is selected from the group consisting of: isovaleric acid, a pharmaceutically acceptable salt of isovaleric acid, a pharmaceutically acceptable ester of isovaleric acid, an active compound having the structure:



wherein

- A = H, CH₃, or OH,
- B = H, OH, or CH₃,
- X = CH₂, CHCH₃, C(CH₃)₂, -O-, CH(OH), or -CH₂O-,
- Y = -CO-, or -SO₂-, and
- Z = H, CH₂CO₂H, or CH₂CONH₂,

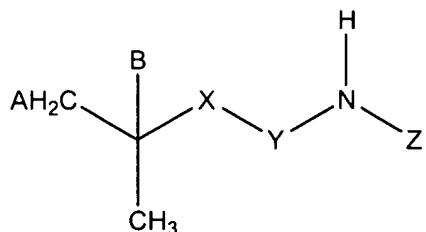
and a compound selected from the group consisting of isovaleramide, 2-methylisovaleramide, 3-methylisovaleramide, 2,2-dimethylisovaleramide, 2,3-dimethylisovaleramide, 4-methylisovaleramide, 2,4-dimethylisovaleramide, 3,4-dimethylisovaleramide, 2,2,4-trimethylisovaleramide, 3-hydroxyisovaleramide, 4-hydroxyisovaleramide, 4-hydroxy-3-methylisovaleramide, 2-hydroxyisovaleramide, N-(2-acetamido)isovaleramide, 2-methyl-1-propylsulfonamide, 1-methylethyl sulfamate, 2-methyl-1-propyl sulfamate, isopropyl carbamate, and isobutylcarbamate.

49. (Currently amended) A-The process according to claim 48, wherein said-the gelling agent comprises xanthan gum.

50. (Currently amended) A-The process according to claim 48, further comprising the step of coating the core matrix with a polymer solution to form a film coating.

51. (Currently amended) A method of treating a pathology that is ameliorated by a modulation of CNS activity, wherein said-the pathology is selected from the group consisting of

convulsions, spasticity, affective mood disorder, neuropathic pain syndrome, headache, restlessness syndrome, movement disorder substance abuse/craving disorder, substance abuse, craving, and cerebral trauma, comprising administering to a patient suffering from said the pathology an oral sustained-release pharmaceutical composition comprising a core matrix comprising (1) a therapeutically effective amount of an active compound and (2) a gelling agent, wherein the amount of said the active compound represents from about 40-70% 40% to about 70% by weight of the oral sustained-release pharmaceutical composition, and wherein said the active compound is selected from the group consisting of: isovaleric acid, a pharmaceutically acceptable salt of isovaleric acid, a pharmaceutically acceptable ester of isovaleric acid, isovaleramide, a active compound having the structure:



wherein

AH ₂ C	A = H, CH ₃ , or OH,
B	B = H, OH, or CH ₃ ,
X	X = CH ₂ , CHCH ₃ , C(CH ₃) ₂ , -O-, CH(OH), or -CH ₂ O-,
Y	Y = -CO-, or -SO ₂ -, and
Z	Z = H, CH ₂ CO ₂ H, or CH ₂ CONH ₂ ,

and a compound selected from the group consisting of 2-methylisovaleramide, 3-methylisovaleramide, 2,2-dimethylisovaleramide, 2,3-dimethylisovaleramide, 4-methylisovaleramide, 2,4-dimethylisovaleramide, 3,4-dimethylisovaleramide, 2,2,4-trimethylisovaleramide, 3-hydroxyisovaleramide, 4-hydroxyisovaleramide, 4-hydroxy-3-methylisovaleramide, 2-hydroxyisovaleramide, N-(2-acetamido)isovaleramide, 2-methyl-1-propyl sulfonamide, 1-methylethyl sulfamate, 2-methyl-1-propyl sulfamate, isopropyl carbamate, and isobutylcarbamate,

with the proviso that the treated pathology is not convulsions when the compound is 3-methylisovaleramide, isopropyl carbamate, or isobutyl carbamate.

52. (Currently amended) ~~A-The~~ method according to claim 51, wherein ~~said the oral~~ sustained-release pharmaceutical composition is in tablet form and the tablet contains a therapeutically effective unit dose of the active compound.

53. (Currently amended) ~~A-The~~ method according to claim 51, wherein ~~said the oral~~ sustained-release pharmaceutical composition is a multiparticulate composition and the multiparticulate composition contains a therapeutically effective unit dose of the active compound.

54. (Currently amended) ~~A composition-The~~ method according to claim 51, wherein ~~said the~~ gelling agent comprises xanthan gum.

55. (Currently amended) ~~A-The~~ method according to claim 51, wherein ~~said the oral~~ sustained-release pharmaceutical composition further comprises a film-coating comprising a polymeric coating material.

Claim 56 (Canceled)

57. (Currently amended) ~~A-The~~ method according to claim 51, wherein ~~said the~~ active compound is isovaleramide.

Claims 58 and 59 (Canceled)